

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
7 April 2005 (07.04.2005)

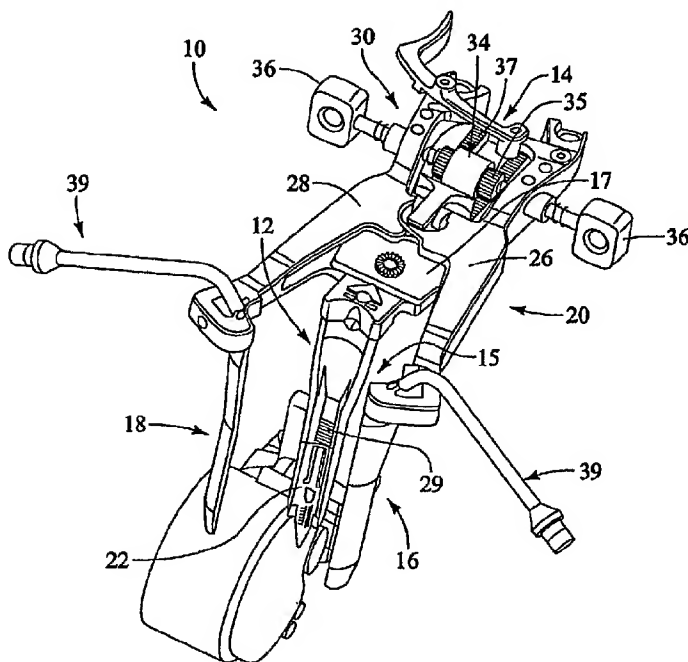
PCT

(10) International Publication Number
WO 2005/030318 A1

- (51) International Patent Classification⁷: **A61N 1/00** (72) Inventor: **BLEWETT, Jeffrey** (deceased).
- (21) International Application Number: PCT/US2004/031768 (72) Inventors; and
(75) Inventors/Applicants (for US only): **MILES, Patrick** [US/US]; 5227 Greenwillow Lane, San Diego, CA 92130 (US). **MARTINELLI, Scot** [US/US]; 9624 Pasao Monril, San Diego, CA 92129 (US). **FINLEY, Eric** [US/US]; 10548 Caminito Banyon, San Diego, CA 92131 (US). **ARAMBULA, Jared** [US/US]; 10065 Old Grove Road, San Diego, CA 92131 (US). **GHARIB, James** [US/US]; 10918 Derrydown Way, San Diego, CA 92130 (US). **FARQUHAR, Allen** [US/US]; 6220 Hannon Court, San Diego, CA 92117 (US). **KAULA, Norbert** [DE/US]; 8258 West 72nd Avenue, Arvada, CO 80005 (US).
- (22) International Filing Date: 27 September 2004 (27.09.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/506,136 25 September 2003 (25.09.2003) US
- (71) Applicant (for all designated States except US): **NUVASIVE, INC.** [US/US]; 10065 Old Grove Avenue, San Diego, CA 92131 (US).
- (71) Applicant (for US only): **MEDEIROS, Goretti** (heirress of the deceased inventor) [US/US]; 86 Parkview Drive, Plantsville, CT 06479 (US).
- (74) Agent: **SPANGLER, Jonathan**; NuVasive Inc., 10065 Old Grove Road, San Diego, CA 92131 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE,

[Continued on next page]

(54) Title: SURGICAL ACCESS SYSTEM AND RELATED METHODS



(57) Abstract: A surgical access system including a tissue distraction assembly and a tissue retraction assembly (10), both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor to a surgical target site.



KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI,

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SURGICAL ACCESS SYSTEM AND RELATED METHODS

Cross Reference to Related Applications

The present application is an International Patent Application of and claims
5 the benefit of priority from commonly owned and co-pending U.S. Provisional Patent
Applications Serial Nos. 60/506,136 (filed September 25, 2003), the entire contents
of which is hereby expressly incorporated by reference into this disclosure as if set
forth fully herein. The present application also incorporates by reference the
following co-pending and co-assigned patent applications in their entireties: PCT
10 App. Ser. No. PCT/US02/22247, entitled "System and Methods for Determining
Nerve Proximity, Direction, and Pathology During Surgery," filed on July 11, 2002;
PCT App. Ser. No. PCT/US02/30617, entitled "System and Methods for Performing
Surgical Procedures and Assessments," filed on Sept. 25, 2002; PCT App. Ser. No.
PCT/US02/35047, entitled "System and Methods for Performing Percutaneous
15 Pedicle Integrity Assessments," filed on October 30, 2002; and PCT App. Ser. No.
PCT/US03/02056, entitled "System and Methods for Determining Nerve Direction to
a Surgical Instrument," filed January 15, 2003 (collectively "NeuroVision PCT
Applications").

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to systems and methods for
5 performing surgical procedures and, more particularly, for accessing a surgical target
site in order to perform surgical procedures.

II. Discussion of the Prior Art

A noteworthy trend in the medical community is the move away from
10 performing surgery via traditional “open” techniques in favor of minimally invasive
or minimal access techniques. Open surgical techniques are generally undesirable in
that they typically require large incisions and high amounts of tissue displacement to
gain access to the surgical target site, which produces concomitantly high amounts of
pain, lengthened hospitalization (increasing health care costs), and high morbidity in
15 the patient population. Less-invasive surgical techniques (including so-called
“minimal access” and “minimally invasive” techniques) are gaining favor due to the
fact that they involve accessing the surgical target site via incisions of substantially
smaller size with greatly reduced tissue displacement requirements. This, in turn,
reduces the pain, morbidity and cost associated with such procedures. The access
20 systems developed to date, however, fail in various respects to meet all the needs of
the surgeon population.

One drawback associated with prior art surgical access systems relates to the ease with which the operative corridor can be created, as well as maintained over time, depending upon the particular surgical target site. For example, when
5 accessing surgical target sites located beneath or behind musculature or other relatively strong tissue (such as, by way of example only, the psoas muscle adjacent to the spine), it has been found that advancing an operative corridor-establishing instrument directly through such tissues can be challenging and/or lead to unwanted or undesirable effects (such as stressing or tearing the tissues). While certain efforts
10 have been undertaken to reduce the trauma to tissue while creating an operative corridor, such as (by way of example only) the sequential dilation system of US Pat No. 5,792,044 to Foley et al., these attempts are nonetheless limited in their applicability based on the relatively narrow operative corridor. More specifically, based on the generally cylindrical nature of the so-called "working cannula," the
15 degree to which instruments can be manipulated and/or angled within the cannula can be generally limited or restrictive, particularly if the surgical target site is a relatively deep within the patient.

Efforts have been undertaken to overcome this drawback, such as shown in
20 US Pat No 6,524,320 to DiPoto, wherein an expandable portion is provided at the distal end of a cannula for creating a region of increased cross-sectional area adjacent

to the surgical target site. While this system may provide for improved instrument manipulation relative to sequential dilation access systems (at least at deep sites within the patient), it is nonetheless flawed in that the deployment of the expandable portion may inadvertently compress or impinge upon sensitive tissues adjacent to the surgical target site. For example, in anatomical regions having neural and/or vasculature structures, such a blind expansion may cause the expandable portion to impinge upon these sensitive tissues and cause neural and/or vasculature compromise, damage and/or pain for the patient.

10 This highlights yet another drawback with the prior art surgical access systems, namely, the challenges in establishing an operative corridor through or near tissue having major neural structures which, if contacted or impinged, may result in neural impairment for the patient. Due to the threat of contacting such neural structures, efforts thus far have largely restricted to establishing operative corridors
15 through tissue having little or substantially reduced neural structures, which effectively limits the number of ways a given surgical target site can be accessed. This can be seen, by way of example only, in the spinal arts, where the exiting nerve roots and neural plexus structures in the psoas muscle have rendered a lateral or far lateral access path (so-called trans-psoas approach) to the lumbar spine virtually
20 impossible. Instead, spine surgeons are largely restricted to accessing the spine from the posterior (to perform, among other procedures, posterior lumbar interbody fusion

(PLIF)) or from the anterior (to perform, among other procedures, anterior lumbar interbody fusion (ALIF)).

Posterior-access procedures involve traversing a shorter distance within the patient to establish the operative corridor, albeit at the price of oftentimes having to reduce or cut away part of the posterior bony structures (i.e. lamina, facets, spinous process) in order to reach the target site (which typically comprises the disc space). Anterior-access procedures are relatively simple for surgeons in that they do not involve reducing or cutting away bony structures to reach the surgical target site. However, they are nonetheless disadvantageous in that they require traversing through a much greater distance within the patient to establish the operative corridor, oftentimes requiring an additional surgeon to assist with moving the various internal organs out of the way to create the operative corridor.

The present invention is directed at eliminating, or at least minimizing the effects of, the above-identified drawbacks in the prior art.

SUMMARY OF THE INVENTION

The present invention accomplishes this goal by providing a novel access system and related methods which involve detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the

establishment of an operative corridor through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the access system of the present invention is suitable for use in any number of additional surgical procedures wherein tissue having significant neural structures must be passed through (or near) in order to establish an operative corridor.

According to one broad aspect of the present invention, the access system comprises a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures. The tissue distraction assembly (in conjunction with one or more elements of the tissue retraction assembly) is capable of, as an initial step, distracting a region of tissue between the skin of the patient and the surgical target site. The tissue retraction assembly is capable of, as a secondary step, being introduced into this distracted region to thereby define and establish the operative corridor. Once established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure. The electrode(s) are capable of, during both tissue distraction and retraction, detecting the existence of (and optionally the distance and/or direction to)

neural structures such that the operative corridor may be established through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access system of the present invention may be used to traverse tissue that would
5 ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly may include any number of components capable of performing the necessary distraction. By way of example only, the tissue
10 distraction assembly may include a K-wire, an initial dilator of split construction, and one or more dilators of traditional (that is, non-split) construction for performing the necessary tissue distraction to receive the remainder of the tissue retractor assembly thereafter. One or more electrodes may be provided on one or more of the K-wire and dilator(s) to detect the presence of (and optionally the distance and/or direction
15 to) neural structures during tissue distraction.

The tissue retraction assembly may include any number of components capable of performing the necessary retraction. By way of example only, the tissue retraction assembly may include one or more retractor blades extending from a
20 handle assembly. The handle assembly may be manipulated to open the retractor assembly; that is, allowing the retractor blades to separate from one another

(simultaneously or sequentially) to create an operative corridor to the surgical target site. In a preferred embodiment, this is accomplished by maintaining a posterior retractor blade in a fixed position relative to the surgical target site (so as to avoid having it impinge upon any exiting nerve roots near the posterior elements of the spine) while the additional retractor blades (i.e. cephalad-most and caudal-most blades) are moved or otherwise translated away from the posterior retractor blade (and each other) so as to create the operative corridor in a fashion that doesn't infringe upon the region of the exiting nerve roots.

10 The retractor blades may be optionally dimensioned to receive and direct a rigid shim element to augment the structural stability of the retractor blades and thereby ensure the operative corridor, once established, will not decrease or become more restricted, such as may result if distal ends of the retractor blades were permitted to "slide" or otherwise move in response to the force exerted by the displaced tissue. In a preferred embodiment, only the posterior retractor blade is 15 equipped with such a rigid shim element. In an optional aspect, this shim element may be advanced into the disc space after the posterior retractor blade is positioned, but before the retractor is opened into the fully retracted position. The rigid shim element is preferably oriented within the disc space such that it distracts the adjacent 20 vertebral bodies, which serves to restore disc height. It also preferably advances a sufficient distance within the disc space (preferably past the midline), which serves

the dual purpose of preventing post-operative scoliosis and forming a protective barrier (preventing the migration of tissue (such as nerve roots) into the operative field and the inadvertent advancement of instruments outside the operative field).

- 5 The retractor blades may optionally be equipped with a mechanism for transporting or emitting light at or near the surgical target site to aid the surgeon's ability to visualize the surgical target site, instruments and/or implants during the given surgical procedure. According to one embodiment, this mechanism may comprise, but need not be limited to, coupling one or more light sources to the
- 10 retractor blades such that the terminal ends are capable of emitting light at or near the surgical target site. According to another embodiment, this mechanism may comprise, but need not be limited to, constructing the retractor blades of suitable material (such as clear polycarbonate) and configuration such that light may be transmitted generally distally through the walls of the retractor blade light to shine
- 15 light at or near the surgical target site. This may be performed by providing the retractor blades having light-transmission characteristics (such as with clear polycarbonate construction) and transmitting the light almost entirely within the walls of the retractor blade (such as by frosting or otherwise rendering opaque portions of the exterior and/or interior) until it exits a portion along the interior (or
- 20 medially-facing) surface of the retractor blade to shine at or near the surgical target site. The exit portion may be optimally configured such that the light is directed

towards the approximate center of the surgical target site and may be provided along the entire inner periphery of the retractor blade or one or more portions therealong.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Many advantages of the present invention will be apparent to those skilled in the art with a reading of this specification in conjunction with the attached drawings, wherein like reference numerals are applied to like elements and wherein:

Figure 1 is a perspective view of a tissue retraction assembly (in use) forming
10 part of a surgical access system according to the present invention;

FIGS. 2-3 are perspective views illustrating the front and back of a shim
element for use with a posterior retractor blade of the retractor according to the
retractor of the present invention;

15 FIGS. 4-5 are perspective views illustrating the front and back of a narrow retractor extender for use with one of a cephalad and caudal retractor blade according to the retractor of the present invention;

FIGS. 6-7 are perspective views illustrating the front and back of a wide retractor extender for use with one of a cephalad and caudal retractor blade according to the retractor of the present invention;

5 FIG. 8 is a perspective, partially exploded view of the retractor assembly of the present invention, without the retractor blades;

FIG. 9 is a perspective view illustrating the components and use of an initial distraction assembly (i.e. K-wire, an initial dilating cannula with handle, and a split-dilator housed within the initial dilating cannula) forming part of the surgical access system according to the present invention, for use in distracting to a surgical target site (i.e. annulus);

10

FIG. 10 is a perspective view illustrating the K-wire and split-dilator of the initial distraction assembly with the initial dilating cannula and handle removed;

15

FIG. 11 is a posterior view of the vertebral target site illustrating the split-dilator of the present invention in use distracting in a generally cephalad-caudal fashion according to one aspect of the present invention;

20

FIG. 12 is a side view illustrating the use of a secondary distraction assembly (comprising a plurality of dilating cannulae over the K-wire) to further distract tissue between the skin of the patient and the surgical target site according to the present invention;

5

FIG. 13 is a side view of a retractor assembly according to the present invention, comprising a handle assembly having three (3) retractor blades extending there from (posterior, cephalad-most, and caudal-most) disposed over the secondary distraction assembly of FIG. 12 (shown in a first, closed position);

10

FIG. 14 is a side view of a retractor assembly according to the present invention, comprising a handle assembly having three (3) retractor blades extending there from (posterior, cephalad-most, and caudal-most) with the secondary distraction assembly of FIG. 12 removed and shim element introduced;

15

FIGS. 15-16 are perspective and top views, respectively, of the retractor assembly in a second, opened (i.e. retracted) position to thereby create an operative corridor to a surgical target site according to the present invention;

20

FIGS. 17-18 are perspective and side views, respectively, of the retractor assembly in the second, opened (i.e. retracted) position (with the secondary

distraction assembly removed) and with the retractor extenders of FIGS. 4-5 and 6-7 coupled to the retractor according to the present invention.

Figure 19 is a perspective view of an exemplary nerve monitoring system
5 capable of performing nerve monitoring before, during and after the creating of an operative corridor to a surgical target site using the surgical access system in accordance with the present invention;

Figure 20 is a block diagram of the nerve monitoring system shown in FIG.
10 19; and

Figures 21-22 are screen displays illustrating exemplary features and information communicated to a user during the use of the nerve monitoring system of FIG. 19.

15

DESCRIPTION OF THE PREFERRED EMBODIMENT

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such
20 actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and

business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. It is furthermore to be
5 readily understood that, although discussed below primarily within the context of spinal surgery, the surgical access system of the present invention may be employed in any number of anatomical settings to provide access to any number of different surgical target sites throughout the body. The surgical access system disclosed herein boasts a variety of inventive features and components that warrant patent
10 protection, both individually and in combination.

The present invention involves accessing a surgical target site in a fashion less invasive than traditional "open" surgeries and doing so in a manner that provides access in spite of the neural structures required to be passed through (or near) in
15 order to establish an operative corridor to the surgical target site. Generally speaking, the surgical access system of the present invention accomplishes this by providing a tissue distraction assembly and a tissue retraction assembly, both of which may be equipped with one or more electrodes for use in detecting the existence of (and optionally the distance and/or direction to) neural structures.

20

These electrodes are preferably provided for use with a nerve surveillance system such as, by way of example, the type shown and described in the co-pending and commonly assigned NeuroVision PCT Applications referenced above, the entire contents of which are expressly incorporated by reference as if set forth herein in

5 their entirety. Generally speaking, this nerve surveillance system is capable of detecting the existence of (and optionally the distance and/or direction to) neural structures during the distraction and retraction of tissue by detecting the presence of nerves by applying a stimulation signal to such instruments and monitoring the evoked EMG signals from the myotomes associated with the nerves being passed by

10 the distraction and retraction systems of the present invention. In so doing, the system as a whole (including the surgical access system of the present invention) may be used to form an operative corridor through (or near) any of a variety of tissues having such neural structures, particularly those which, if contacted or impinged, may otherwise result in neural impairment for the patient. In this fashion, the access

15 system of the present invention may be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

The tissue distraction assembly of the present invention (comprising a K-

20 wire, an initial dilator, and a split-dilator disposed within the initial dilator) is employed to distract the tissues extending between the skin of the patient and a given

surgical target site (preferably along the posterior region of the target intervertebral disc). A secondary distraction assembly (i.e. a plurality of sequentially dilating cannulae) may optionally be employed after the initial distraction assembly to further distract the tissue. Once distracted, the resulting void or distracted region within the patient is of sufficient size to accommodate a tissue retraction assembly of the present invention. More specifically, the tissue retraction assembly (comprising a plurality of retractor blades extending from a handle assembly) may be advanced relative to the secondary distraction assembly such that the retractor blades, in a first, closed position, are advanced over the exterior of the secondary distraction assembly. At that point, the handle assembly may be operated to move the retractor blades into a second, open or "retracted" position to create an operative corridor to the surgical target site.

According to one aspect of the invention, following (or before) this retraction, a posterior shim element (which is preferably slideably engaged with the posterior retractor blade) may be advanced such that a distal shim extension is positioned within the posterior region of the disc space. If done before retraction, this helps ensure that the posterior retractor blade will not move posteriorly during the retraction process, even though the other retractor blades (i.e. cephalad-most and caudal-most) are able to move and thereby create an operative corridor. Fixing the posterior retractor blade in this fashion serves several important functions. First, the

distal end of the shim element serves to distract the adjacent vertebral bodies, thereby restoring disc height. It also rigidly couples the posterior retractor blade in fixed relation relative to the vertebral bodies. The posterior shim element also helps ensure that surgical instruments employed within the operative corridor are incapable of being advanced outside the operative corridor, preventing inadvertent contact with the exiting nerve roots during the surgery. Once in the appropriate retracted state, the cephalad-most and caudal-most retractor blades may be locked in position and, thereafter, retractor extenders advanced therealong to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc...) into or out of the operative corridor. Once the operative corridor is established, any of a variety of surgical instruments, devices, or implants may be passed through and/or manipulated within the operative corridor depending upon the given surgical procedure.

Figure 1 illustrates a tissue retraction assembly 10 forming part of a surgical access system according to the present invention. The retraction assembly 10 includes a plurality of retractor blades extending from a handle assembly 20. By way of example only, the handle assembly 20 is provided with a first retractor blade 12, a second retractor blade 16, and a third retractor blade 18. The retractor assembly 10 is shown in a fully retracted or "open" configuration, with the retractor blades 12, 16, 18 positioned a distance from one another so as to form an operative corridor 15 there between and extending to a surgical target site (e.g. an annulus of an

intervertebral disc). Although shown and described below with regard to the three-bladed configuration, it is to be readily appreciated that the number of retractor blades may be increased or decreased without departing from the scope of the present invention. Moreover, although described and shown herein with reference to a

5 generally lateral approach to a spinal surgical target site (with the first blade 12 being the “posterior” blade, the second blade 16 being the “cephalad-most” blade, and the third blade 18 being the “caudal-most” blade), it will be appreciated that the retractor assembly 10 of the present invention may find use in any number of different surgical approaches, including generally posterior, generally postero-lateral, generally anterior

10 and generally antero-lateral.

The retractor blades 12, 16, 18 may be equipped with various additional features or components. By way of example only, posterior retractor blade 12 may be equipped with a shim element 22 (shown more clearly in FIGS. 2-3). Shim

15 element 22 serves to distract the adjacent vertebral bodies (thereby restoring disc height), helps secure the retractor assembly 10 relative to the surgical target site, and forms a protective barrier to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc...) into or out of the operative corridor. Each of the remaining retractor blades (cephalad-most blade 16 and caudal-most blade 18)

20 may be equipped with a retractor extender, such as the narrow retractor extender 24 shown in FIGS. 4-5 or the wide retractor extender 25 shown in FIGS. 6-7. The

retractor extenders 24/25 extend from the cephalad-most and caudal-most retractor blades 16, 18 to form a protective barrier to prevent the ingress or egress of instruments or biological structures (i.e. nerves, vasculature, etc...) into or out of the operative corridor 15.

5

According to the present invention, any or all of the retractor blades 12, 16, 18, the shim element 22 and/or the retractor extenders 24/25 may be provided with one or more electrodes 39 (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications. Each of the shim element 22 and/or the retractor extenders 24/25 may also be equipped with a mechanism to selectively and releasably engage with the respective retractor blades 12, 16, 18. By way of example only, this may be accomplished by configuring the shim element 22 and/or the retractor extenders 24/25 with a tab element 27 capable of engaging with corresponding ratchet-like grooves (shown at 29 in FIG. 1) along the inner-facing surfaces of the retractor blades 12, 16, 18. Each of the shim element 22 and/or the retractor extenders 24/25 is provided with a pair of engagement elements 37 having, by way of example only, a generally dove-tailed cross-sectional shape. The engagement elements 37 are dimensioned to engage with receiving portions on the respective retractor blades 12, 16, 18. In a preferred embodiment, each of the shim element 22 and/or the retractor extenders 24/25 are provided with an elongate slot 43

for engagement with an insertion tool (not shown). Each tab member 27 is also equipped with an enlarged tooth element 49 which engages within corresponding grooves 29 provided along the inner surface of the retractor blades 12, 16, 18.

5 The handle assembly 20 may be coupled to any number of mechanisms for rigidly registering the handle assembly 20 in fixed relation to the operative site, such as through the use of an articulating arm mounted to the operating table. The handle assembly 20 includes first and second arm members 26, 28 hingedly coupled via coupling mechanism shown generally at 30. The cephalad-most retractor blade 16 is
10 rigidly coupled (generally perpendicularly) to the end of the first arm member 26. The caudal-most retractor blade 18 is rigidly coupled (generally perpendicularly) to the end of the second arm member 28. The posterior retractor blade 12 is rigidly coupled (generally perpendicularly to) a translating member 17, which is coupled to the handle assembly 20 via a linkage assembly shown generally at 14. The linkage
15 assembly 14 includes a roller member 34 having a pair of manual knob members 36 which, when rotated via manual actuation by a user, causes teeth 35 on the roller member 34 to engage within ratchet-like grooves 37 in the translating member 17. Thus, manual operation of the knobs 36 causes the translating member 17 to move relative to the first and second arm members 26, 28.

20

Through the use of handle extenders 31, 33 (FIG. 8), the arms 26, 28 may be simultaneously opened such that the cephalad-most and caudal-most retractor blades 16, 18 move away from one another. In this fashion, the dimension and/or shape of the operative corridor 15 may be tailored depending upon the degree to which the translating member 17 is manipulated relative to the arms 26, 28. That is, the operative corridor 15 may be tailored to provide any number of suitable cross-sectional shapes, including but not limited to a generally circular cross-section, a generally ellipsoidal cross-section, and/or an oval cross-section. Optional light emitting devices 39 may be coupled to one or more of the retractor blades 12, 16, 18 to direct light down the operative corridor 15.

Figure 9 illustrates an initial distraction assembly 40 forming part of the surgical access system according to the present invention. The initial distraction assembly 40 includes a K-wire 42, an initial dilating cannula 44 with handle 46, and a split-dilator 48 housed within the initial dilating cannula 44. In use, the K-wire 42 and split-dilator 48 are disposed within the initial dilating cannula 44 and the entire assembly 40 advanced through the tissue towards the surgical target site (i.e. annulus). Again, this is preferably accomplished while employing the nerve detection and/or direction features described above. After the initial dilating assembly 40 is advanced such that the distal ends of the split-dilator 48 and initial dilator 44 are positioned within the disc space (FIG. 9), the initial dilator 44 and

handle 46 are removed (FIG. 10) to thereby leave the split-dilator 48 and K-wire 42 in place. As shown in FIG. 11, the split-dilator 48 is thereafter split such that the respective halves 48a, 48b are separated from one another to distract tissue in a generally cephalad-caudal fashion relative to the target site. The split dilator 48 may
5 thereafter be relaxed (allowing the dilator halves 48a, 48b to come together) and rotated such that the dilator halves 48a, 48b are disposed in the anterior-posterior plane. Once rotated in this manner, the dilator halves 48a, 48b are again separated to distract tissue in a generally anterior-posterior fashion. Each dilator halve 48a, 48b may be, according to the present invention, provided with one or more electrodes
10 (preferably at their distal regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications.

Following this initial distraction, a secondary distraction may be optionally
15 undertaken, such as via a sequential dilation system 50 as shown in FIG. 12. According to the present invention, the sequential dilation system 50 may include the K-wire 42, the initial dilator 44, and one or more supplemental dilators 52, 54 for the purpose of further dilating the tissue down to the surgical target site. Once again, each component of the secondary distraction assembly 50 (namely, the K-wire 42,
20 the initial dilator 44, and the supplemental dilators 52, 54 may be, according to the present invention, provided with one or more electrodes (preferably at their distal

regions) equipped for use with a nerve surveillance system, such as, by way of example, the type shown and described in the NeuroVision PCT Applications.

As shown in FIG. 13, the retraction assembly 10 of the present invention is thereafter advanced along the exterior of the sequential dilation system 50. This is accomplished by maintaining the retractor blades 12, 16, 18 in a first, closed position (with the retractor blades 12-16 in generally abutting relation to one another). Once advanced to the surgical target site, the sequential dilation assembly 50 may be removed and the shim element 22 engaged with the posterior retractor blade 12 such that the distal end thereof extends into the disc space as shown in FIG. 14. At this point, the handle assembly 20 may be operated to move the retractor blades 16, 18 into a second, open or "retracted" position as shown generally in FIGS. 15-16. As one can see, the posterior retractor blade 12 is allowed to stay in the same general position during this process, such that the cephalad-most and caudal-most retractor blades 14, 16 move away from the posterior retractor blade 12. At this point, the narrow and wide retractor extenders 24, 25 may be engaged with the caudal-most retractor blade 18 and cephalad-most retractor blade 16, respectively, as shown in FIGS. 17-18.

As mentioned above, any number of distraction components and/or retraction components (including but not limited to those described herein) may be equipped to

detect the presence of (and optionally the distance and/or direction to) neural structures during the steps tissue distraction and/or retraction. This is accomplished by employing the following steps: (1) one or more stimulation electrodes are provided on the various distraction and/or retraction components; (2) a stimulation
5 source (e.g. voltage or current) is coupled to the stimulation electrodes; (3) a stimulation signal is emitted from the stimulation electrodes as the various components are advanced towards or maintained at or near the surgical target site; and (4) the patient is monitored to determine if the stimulation signal causes muscles associated with nerves or neural structures within the tissue to innervate. If the
10 nerves innervate, this may indicate that neural structures may be in close proximity to the distraction and/or retraction components.

Neural monitoring may be accomplished via any number of suitable fashions, including but not limited to observing visual twitches in muscle groups associated
15 with the neural structures likely to found in the tissue, as well as any number of monitoring systems, including but not limited to any commercially available “traditional” electromyography (EMG) system (that is, typically operated by a neurophysiologist). Such monitoring may also be carried out via the surgeon-driven EMG monitoring system shown and described in the following commonly owned
20 and co-pending NeuroVision PCT Applications referenced above. In any case (visual monitoring, traditional EMG and/or surgeon-driven EMG monitoring), the

access system of the present invention may advantageously be used to traverse tissue that would ordinarily be deemed unsafe or undesirable, thereby broadening the number of manners in which a given surgical target site may be accessed.

5 FIGS. 19-20 illustrate, by way of example only, a monitoring system 120 of the type disclosed in the NeuroVision PCT Applications suitable for use with the surgical access system 10 of the present invention. The monitoring system 120 includes a control unit 122, a patient module 124, and an EMG harness 126 and return electrode 128 coupled to the patient module 124, and a cable 132 for
10 establishing electrical communication between the patient module 124 and the surgical access system of the present invention (retractor assembly 10 of FIG. 1 and distraction assemblies 40, 50 of FIGS. 9-12). More specifically, this electrical communication can be achieved by providing, by way of example only, a hand-held stimulation controller 152 capable of selectively providing a stimulation signal (due
15 to the operation of manually operated buttons on the hand-held stimulation controller 152) to one or more connectors 156a, 156b, 156c. The connectors 156a, 156b, 156c are suitable to establish electrical communication between the hand-held stimulation controller 152 and (by way of example only) the stimulation electrodes on the K-wire 42, the dilators 44, 48, 52, 54, the retractor blades 12, 16, 18 and/or the shim
20 members 22, 24, 25 (collectively "surgical access instruments").

In order to use the monitoring system 120, then, these surgical access instruments must be connected to the connectors 156a, 156b and/or 156c, at which point the user may selectively initiate a stimulation signal (preferably, a current signal) from the control unit 122 to a particular surgical access instruments.

- 5 Stimulating the electrode(s) on these surgical access instruments before, during and/or after establishing operative corridor will cause nerves that come into close or relative proximity to the surgical access instruments to depolarize, producing a response in a myotome associated with the innervated nerve.

- 10 The control unit 122 includes a touch screen display 140 and a base 142, which collectively contain the essential processing capabilities (software and/or hardware) for controlling the monitoring system 120. The control unit 122 may include an audio unit 118 that emits sounds according to a location of a surgical element with respect to a nerve. The patient module 124 is connected to the control
- 15 unit 122 via a data cable 144, which establishes the electrical connections and communications (digital and/or analog) between the control unit 122 and patient module 124. The main functions of the control unit 122 include receiving user commands via the touch screen display 140, activating stimulation electrodes on the surgical access instruments, processing signal data according to defined algorithms,
- 20 displaying received parameters and processed data, and monitoring system status and report fault conditions. The touch screen display 140 is preferably equipped with a

graphical user interface (GUI) capable of communicating information to the user and receiving instructions from the user. The display 140 and/or base 142 may contain patient module interface circuitry (hardware and/or software) that commands the stimulation sources, receives digitized signals and other information from the patient module 124, processes the EMG responses to extract characteristic information for each muscle group, and displays the processed data to the operator via the display 140.

In one embodiment, the monitoring system 120 is capable of determining nerve direction relative to one or more of the K-wire 42, the dilators 44, 48, 52, 54, the retractor blades 12, 16, 18 and/or the shim elements 22, 24, 25 before, during and/or following the creation of an operative corridor to a surgical target site. Monitoring system 120 accomplishes this by having the control unit 122 and patient module 124 cooperate to send electrical stimulation signals to one or more of the stimulation electrodes provided on these instruments. Depending upon the location of the surgical access system 10 within a patient (and more particularly, to any neural structures), the stimulation signals may cause nerves adjacent to or in the general proximity of the surgical access system 10 to depolarize. This causes muscle groups to innervate and generate EMG responses, which can be sensed via the EMG harness 126. The nerve direction feature of the system 120 is based on assessing the evoked

response of the various muscle myotomes monitored by the system 120 via the EMG harness 126.

By monitoring the myotomes associated with the nerves (via the EMG harness 126 and recording electrode 127) and assessing the resulting EMG responses (via the control unit 122), the surgical access system 10 is capable of detecting the presence of (and optionally the distant and/or direction to) such nerves. This provides the ability to actively negotiate around or past such nerves to safely and reproducibly form the operative corridor to a particular surgical target site, as well as monitor to ensure that no neural structures migrate into contact with the surgical access system 10 after the operative corridor has been established. In spinal surgery, for example, this is particularly advantageous in that the surgical access system 10 may be particularly suited for establishing an operative corridor to an intervertebral target site in a postero-lateral, trans-psoas fashion so as to avoid the bony posterior elements of the spinal column.

FIGS. 21-22 are exemplary screen displays (to be shown on the display 140) illustrating one embodiment of the nerve direction feature of the monitoring system shown and described with reference to FIGS. 19-20. These screen displays are intended to communicate a variety of information to the surgeon in an easy-to-interpret fashion. This information may include, but is not necessarily limited to, a display of the function 180 (in this case "DIRECTION"), a graphical representation

of a patient 181, the myotome levels being monitored 182, the nerve or group associated with a displayed myotome 183, the name of the instrument being used 184 (in this case, a dilator 46, 48), the size of the instrument being used 185, the stimulation threshold current 186, a graphical representation of the instrument being used 187 (in this case, a cross-sectional view of a dilator 44, 48) to provide a reference point from which to illustrate relative direction of the instrument to the nerve, the stimulation current being applied to the stimulation electrodes 188, instructions for the user 189 (in this case, "ADVANCE" and/or "HOLD"); and (in FIG. 22) an arrow 190 indicating the direction from the instrument to a nerve. This information may be communicated in any number of suitable fashions, including but not limited to the use of visual indicia (such as alpha-numeric characters, light-emitting elements, and/or graphics) and audio communications (such as a speaker element). Although shown with specific reference to a dilating cannula (such as at 184), it is to be readily appreciated that the present invention is deemed to include providing similar information on the display 140 during the use of any or all of the various instruments forming the surgical access system 10 of the present invention, including the initial distraction assembly 40 (i.e. the K-wire 42 and dilators 44, 48) and/or the retractor blades 12, 16, 18 and/or the shim elements 22, 24, 25.

As evident from the above discussion and drawings, the present invention accomplishes the goal of gaining access a surgical target site in a fashion less

invasive than traditional “open” surgeries and, moreover, does so in a manner that provides the ability to access such a surgical target site regardless of the neural structures required to be passed through (or near) in order to establish an operative corridor to the surgical target site. The present invention furthermore provides the

5 ability to perform neural monitoring in the tissue or regions adjacent the surgical target site during any procedures performed after the operative corridor has been established. The surgical access system of the present invention can be used in any of a wide variety of surgical or medical applications, above and beyond the spinal applications discussed herein. Such spinal applications may include any procedure

10 wherein instruments, devices, implants and/or compounds are to be introduced into or adjacent the surgical target site, including but not limited to discectomy, fusion (including PLIF, ALIF, TLIF and any fusion effectuated via a lateral or far-lateral approach and involving, by way of example, the introduction of bone products (such as allograft or autograft) and/or devices having ceramic, metal and/or plastic

15 construction (such as mesh) and/or compounds such as bone morphogenic protein), total disc replacement, etc...).

Moreover, the surgical access system of the present invention opens the possibility of accessing an increased number of surgical target sites in a “less

20 invasive” fashion by eliminating or greatly reducing the threat of contacting nerves or neural structures while establishing an operative corridor through or near tissues

containing such nerves or neural structures. In so doing, the surgical access system of the present invention represents a significant advancement capable of improving patient care (via reduced pain due to “less-invasive” access and reduced or eliminated risk of neural contact before, during, and after the establishment of the operative corridor) and lowering health care costs (via reduced hospitalization based on “less-invasive” access and increased number of suitable surgical target sites based on neural monitoring). Collectively, these translate into major improvements to the overall standard of care available to the patient population, both domestically and overseas.

10

1. A system for accessing a surgical target site, comprising the steps of:
a retractor assembly having a plurality of blades releasably coupled to a
handle assembly, said plurality of blades capable of being advanced simultaneously
to said surgical target site while in a closed position and thereafter selectively opened
5 to create a customized operative corridor to said surgical target site.
2. The system of claim 1, including a distraction assembly for creating a
distraction corridor to said surgical target site prior to advancing said retractor blades
to said surgical target site.
10
3. The system of claim 2, wherein said distraction assembly includes an initial
distraction assembly including a K-wire and at least one dilator capable of being
slideably passed over said K-wire to perform said initial distraction.
- 15 4. The system of claim 3, including a secondary distraction assembly for
distracting said initial distraction corridor to a secondary distraction corridor, said
retractor blades being advanced through said secondary distraction corridor to said
surgical target site.
- 20 5. The system of claim 1 or 2, wherein at least one of said distraction assembly
and at least one of said retractor blades includes at least one stimulation electrode.
6. The system of claim 5, further comprising a control unit capable of
electrically stimulating said at least one stimulation electrode, sensing a response of a
25 nerve depolarized by said stimulation, determining a direction from at least one of
said distraction system and at least one of said retractor blades to the nerve based
upon the sensed response, and communicating said direction to a user.

7. The system of claim 6, further comprising an electrode configured to sense a neuromuscular response of a muscle coupled to said depolarized nerve, the electrode being operable to send the response to the control unit.
- 5 8. The system of claim 3, wherein said K-wire has a first stimulation electrode at a distal tip of the K-wire.
9. The system of claim 1, wherein said system for establishing an operative corridor to a surgical target site is configured to access a spinal target site.
- 10 10. The system of claim 1, wherein said system for establishing an operative corridor to a surgical target site is configured to establish said operative corridor via a lateral, trans-psoas approach.
- 15 11. The system of claim 6, further comprising a handle coupled to at least one of said initial distraction assembly and one of said retractor blades, the handle having at least one button for initiating the electrical stimulation from said control unit to said at least one stimulation electrode.
- 20 12. The system of claim 6, wherein the control unit comprises a display operable to display an electromyographic (EMG) response of the muscle.
13. The system of claim 6, wherein the control unit comprises a touch-screen display operable to receive commands from a user.
- 25 14. The system of claim 6, wherein the stimulation electrodes are positioned near a distal end of at least one of the distraction assembly and at least one of said retractor blades.

15. A method of accessing a surgical target site, comprising the steps of:
simultaneously introducing a plurality of retractor blades to a surgical target
site while in a generally closed position; and
5 selectively moving said retractor blades to create a customized operative
corridor to said surgical target site.
16. The method of claim 15, further comprising the step of creating an initial
10 distraction corridor via the use of a K-wire and at least one dilator capable of being
slideably passed over said K-wire.
17. The method of claim 15, further comprising the step of distracting from said
initial distraction corridor via the use of a secondary distraction assembly to create a
15 secondary distraction corridor.
18. The method of claim 17, wherein said step of performing secondary
distraction system is accomplished via sequential dilation using successively larger
cannulae.
20
19. The method of claim 15, further comprising the step of providing a control
unit capable of electrically stimulating said at least one stimulation electrode, sensing
a response of a nerve depolarized by said stimulation, determining a direction from a
surgical accessory to the nerve based upon the sensed response, and communicating
25 said direction to a user.

1/22

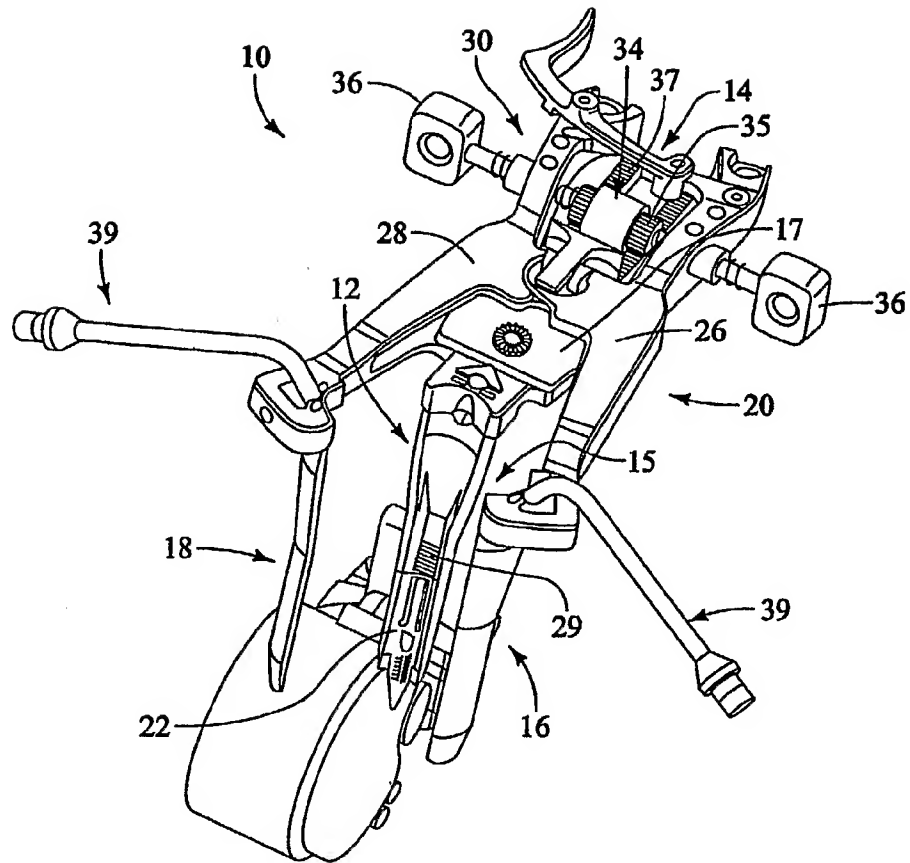


FIG. 1

2/22

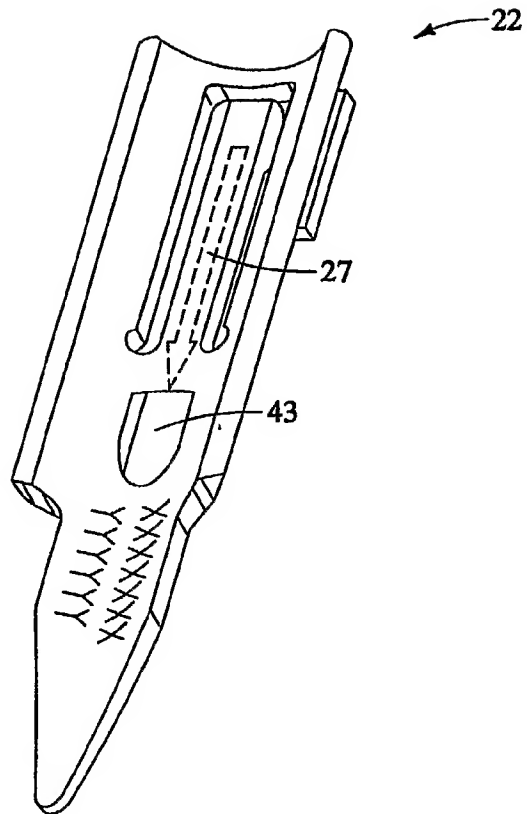


FIG. 2

3/22

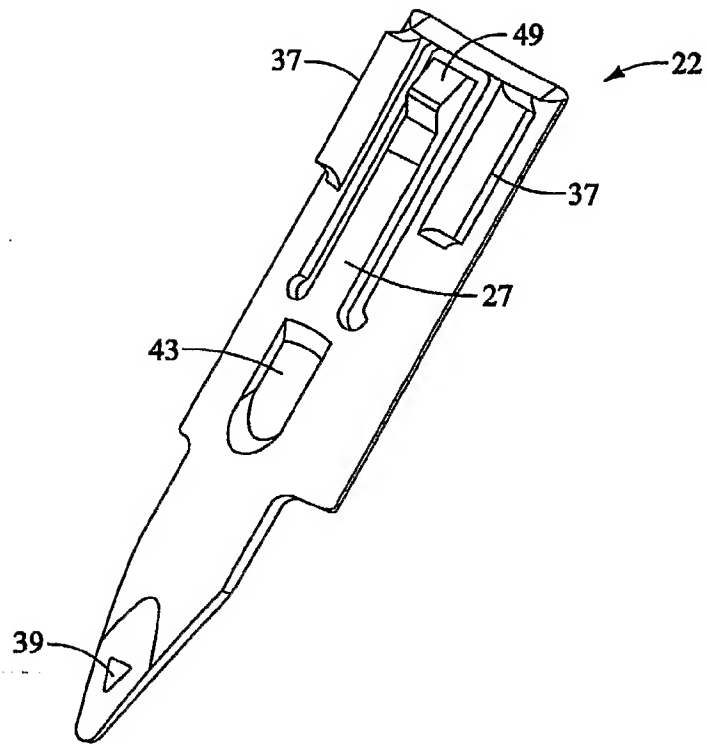


FIG. 3

4/22

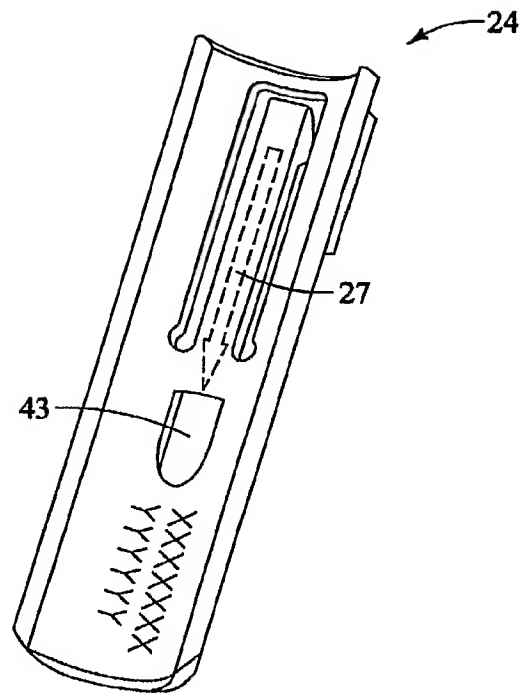


FIG. 4

5/22

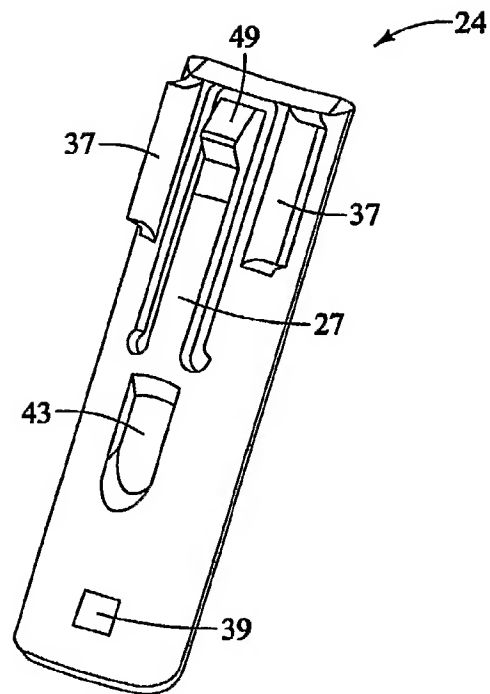


FIG. 5

6/22

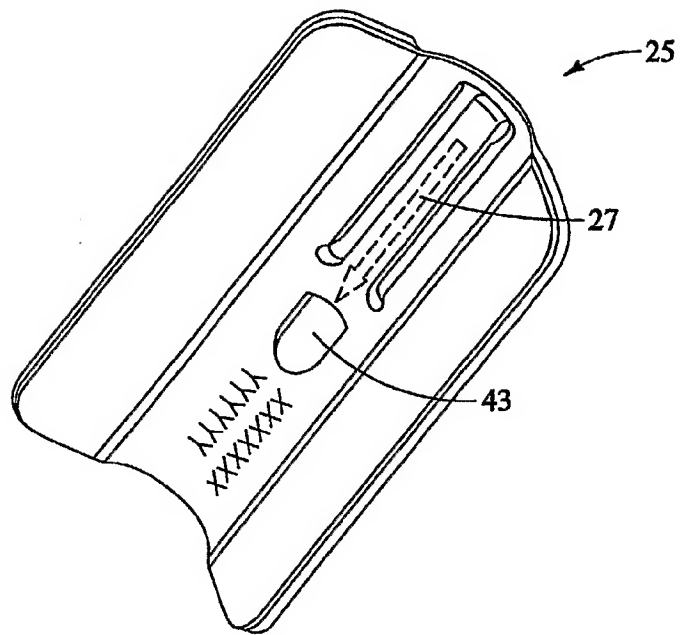


FIG. 6

7/22

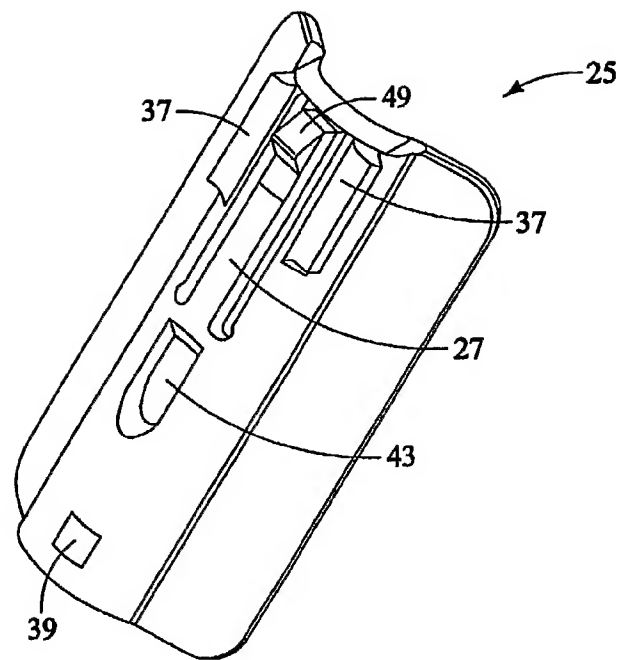


FIG. 7

8/22

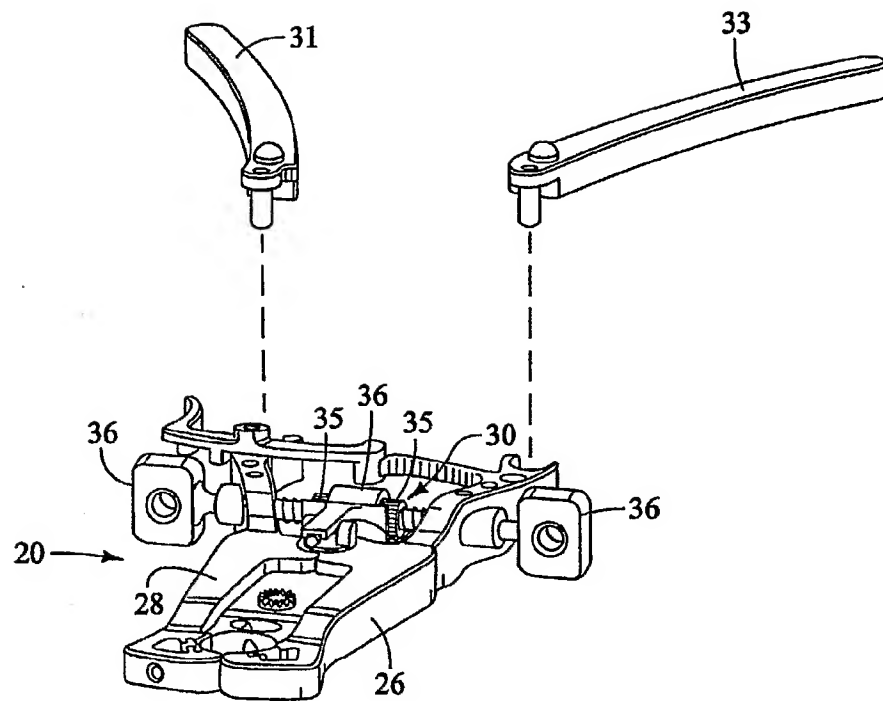


FIG. 8

9/22

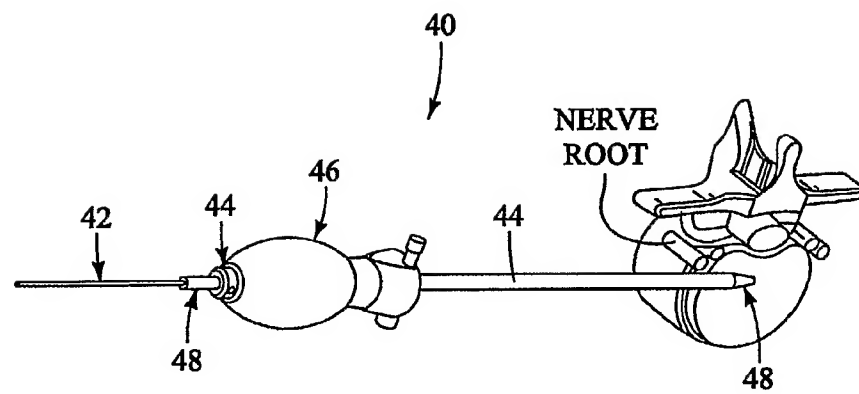


FIG. 9

10/22

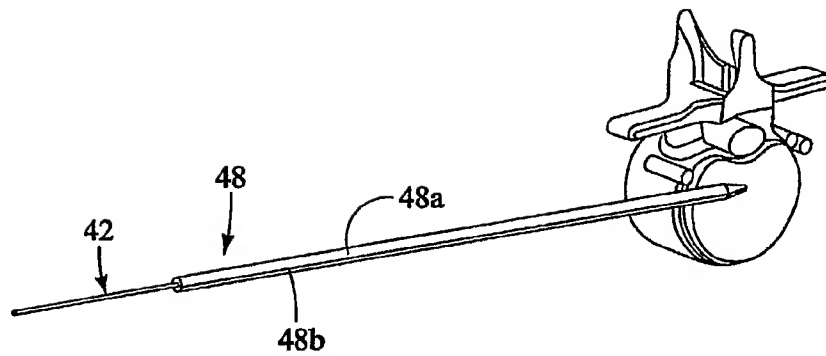


FIG. 10

11/22

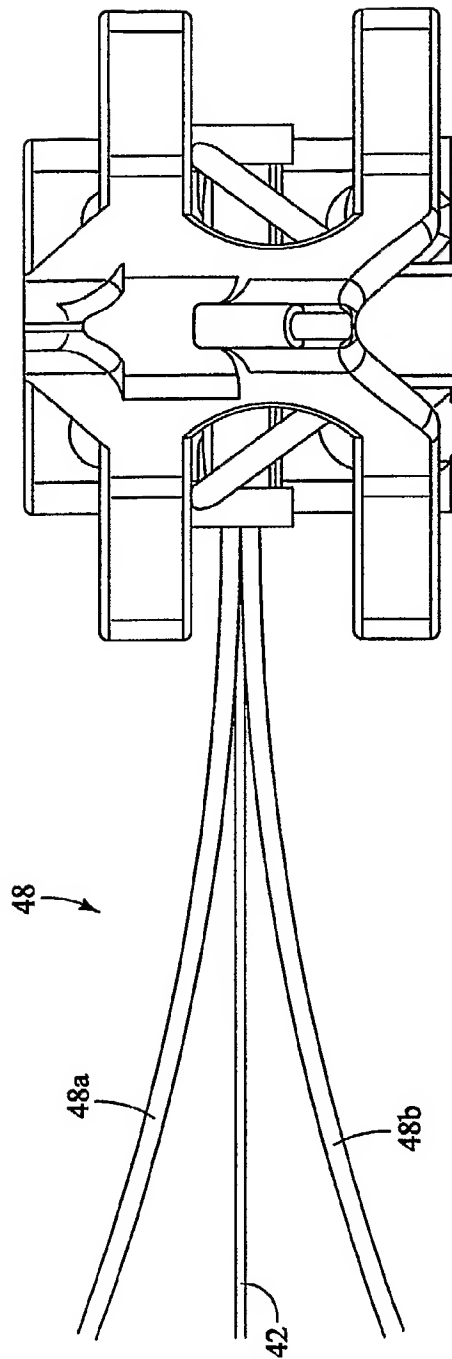


FIG. 11

12/22

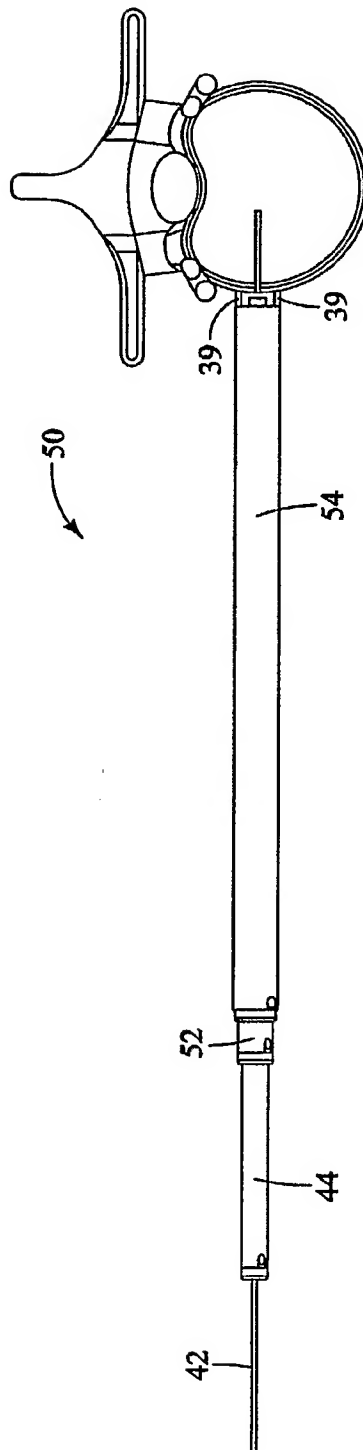


FIG. 12

13/22

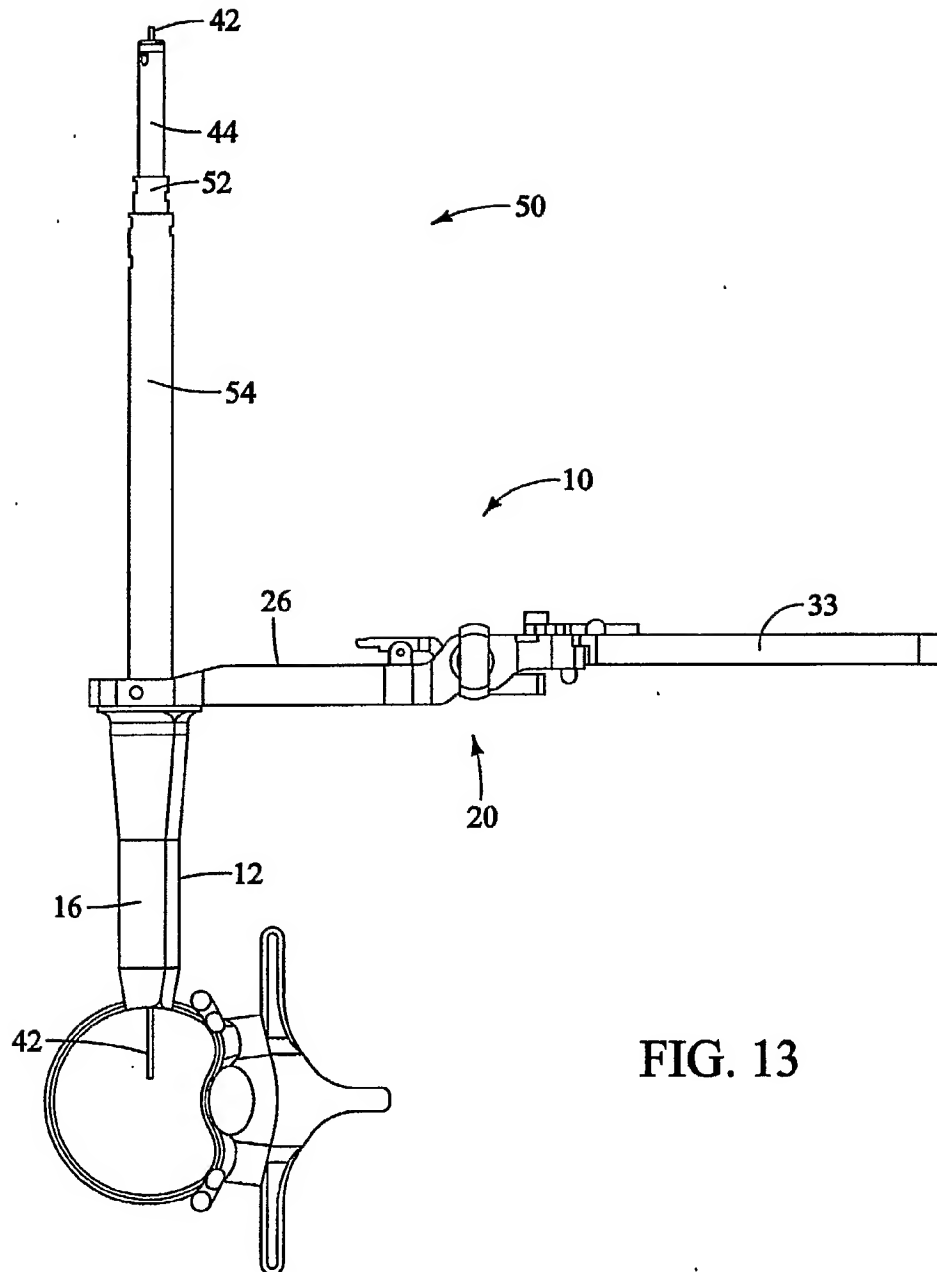


FIG. 13

14/22

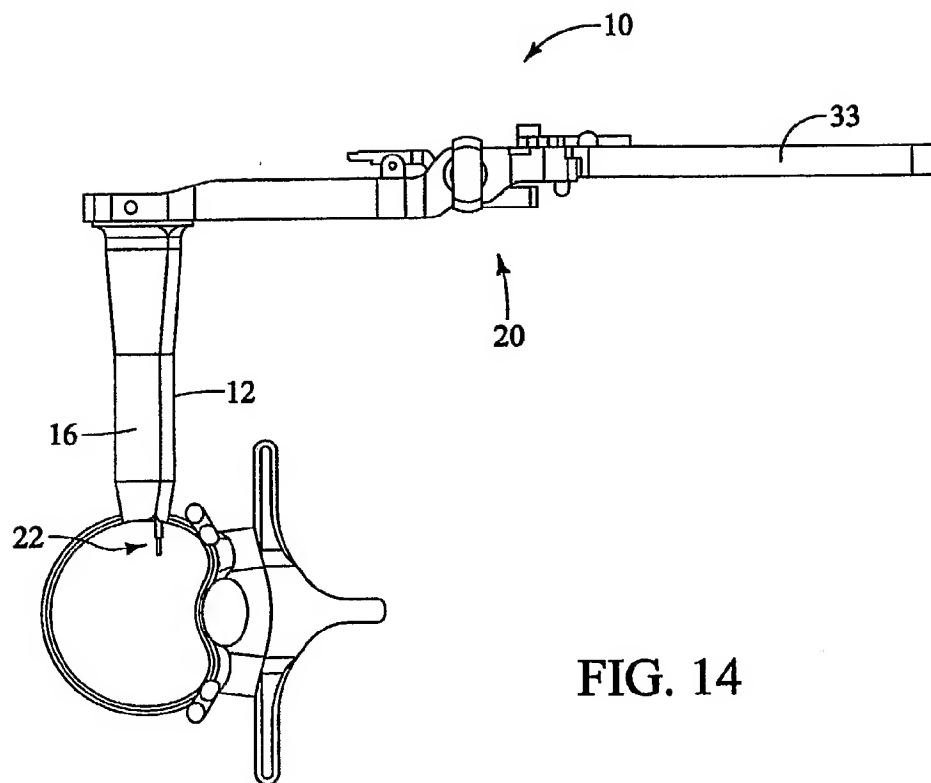


FIG. 14

15/22

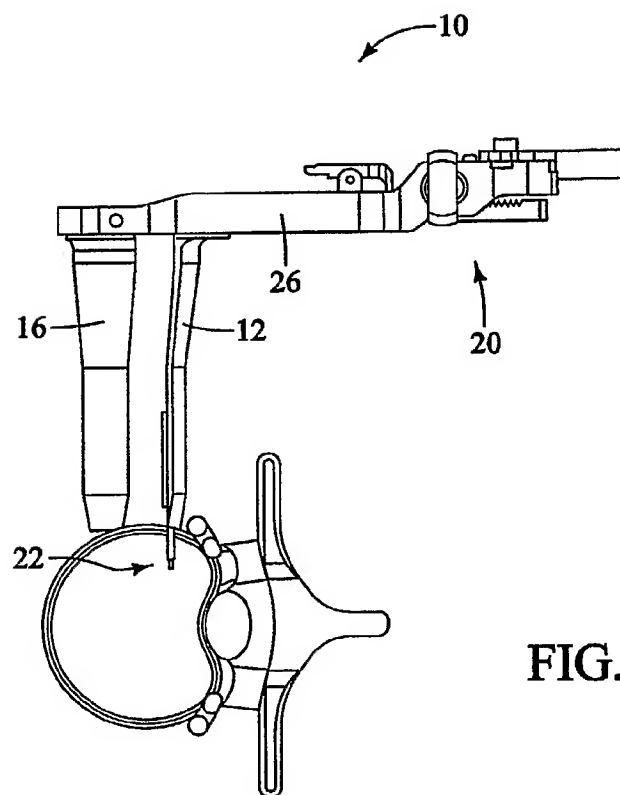


FIG. 15

16/22

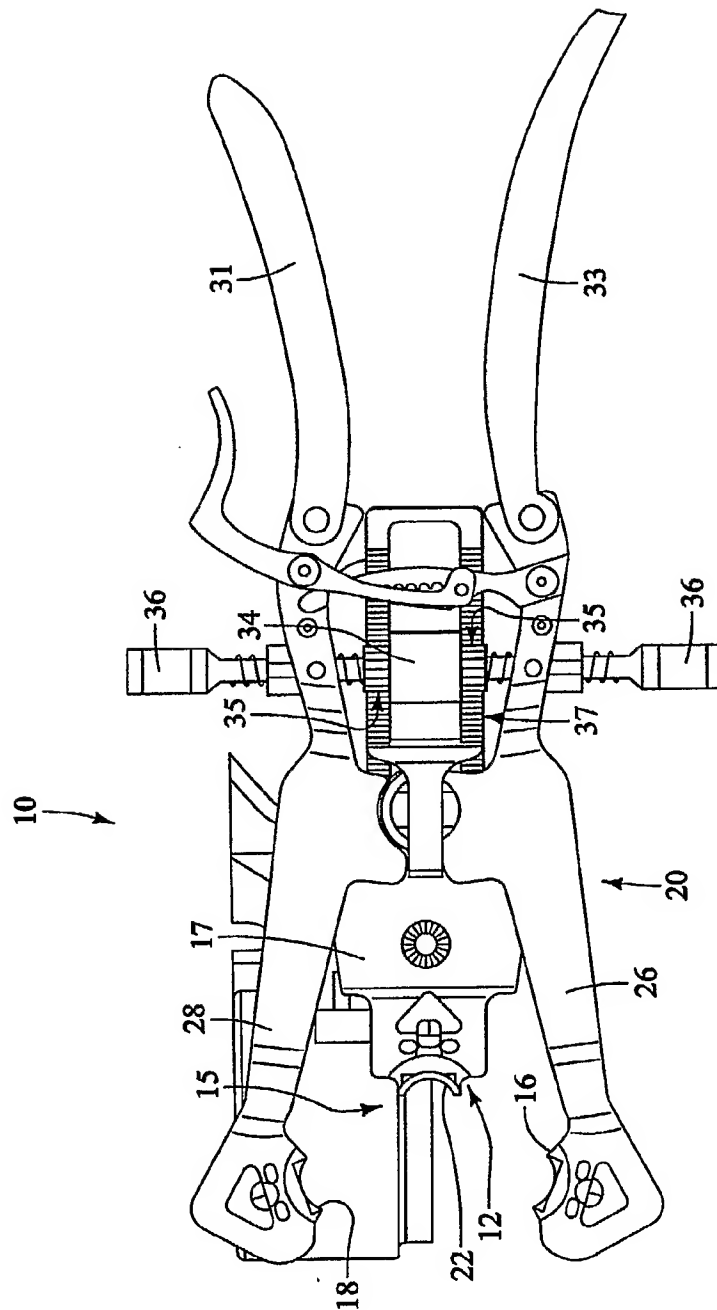


FIG. 16

17/22

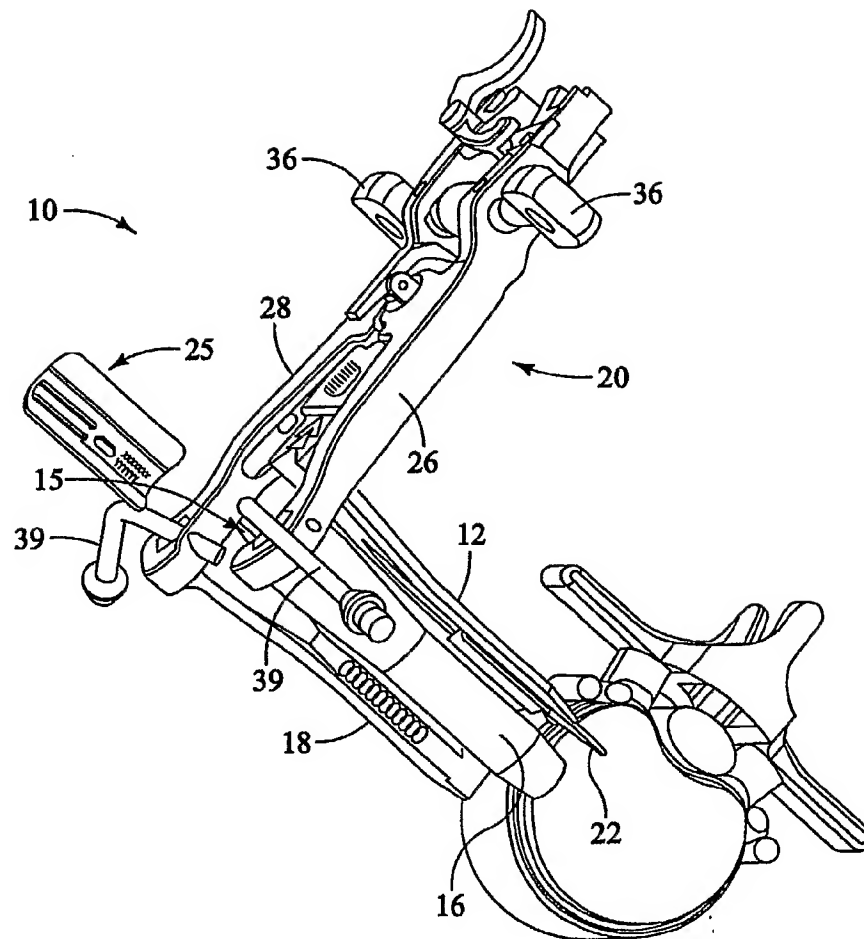


FIG. 17

18/22

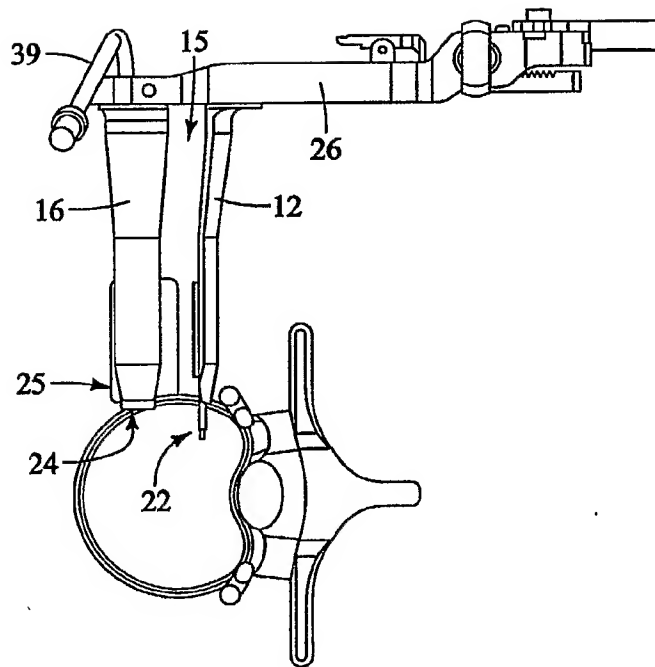


FIG. 18

19/22

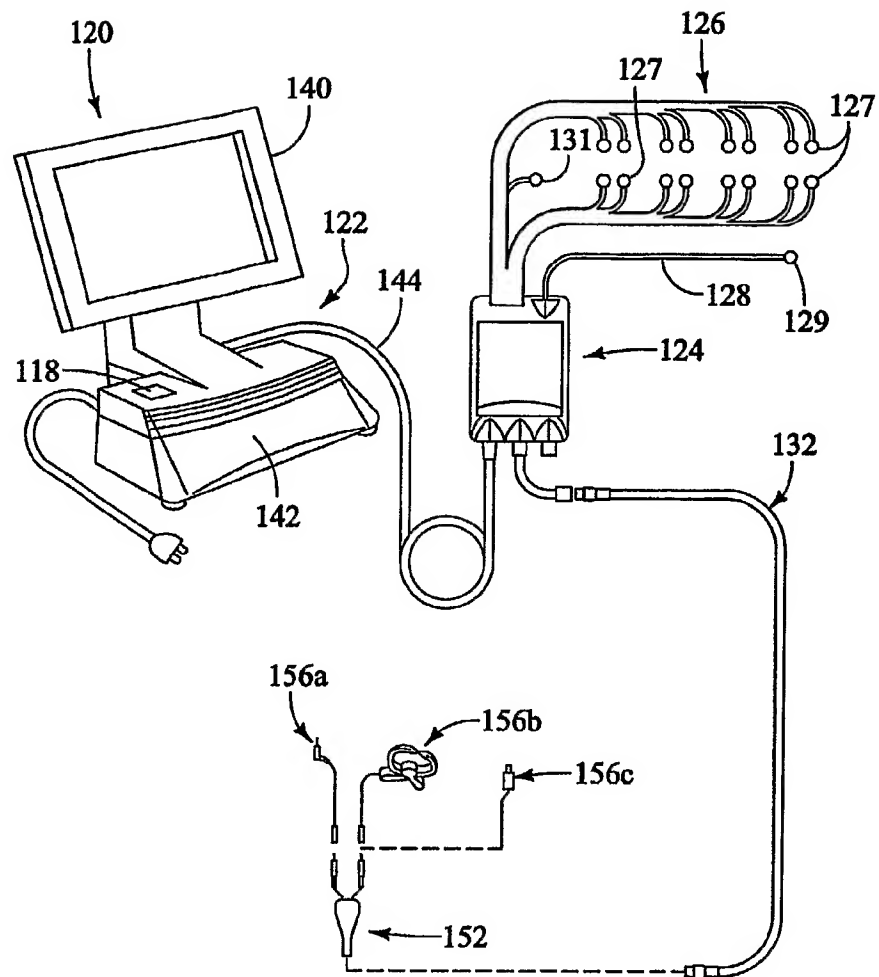


FIG. 19

20/22

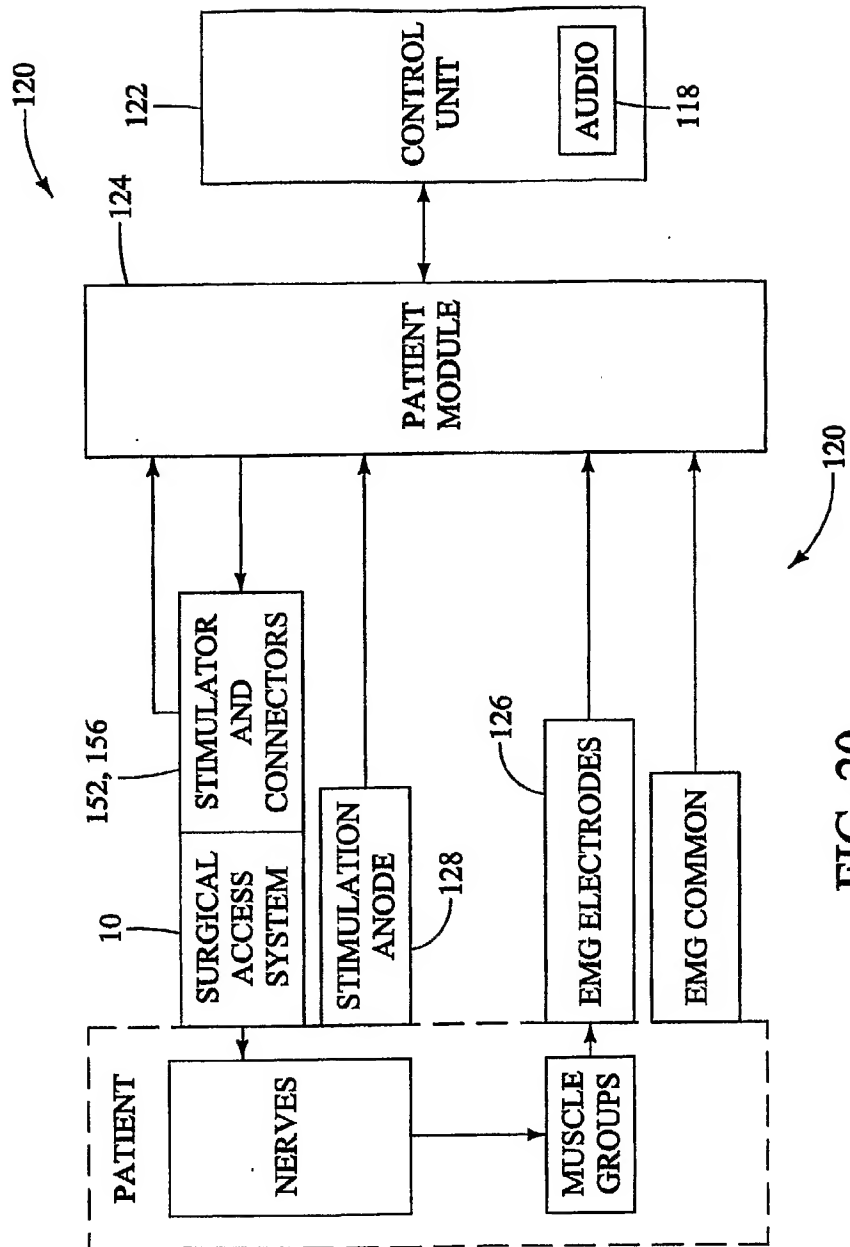
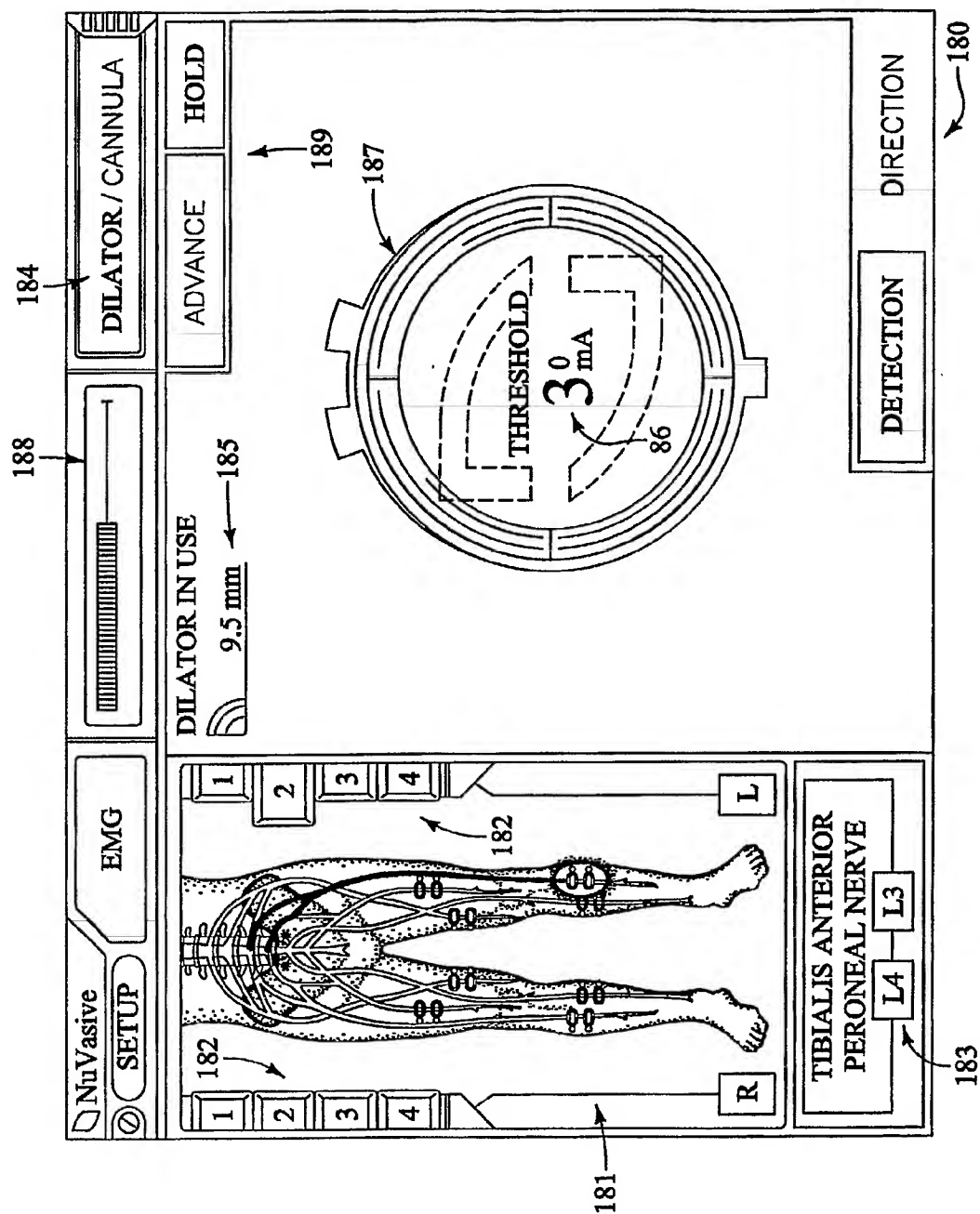


FIG. 20

21/22



22/22

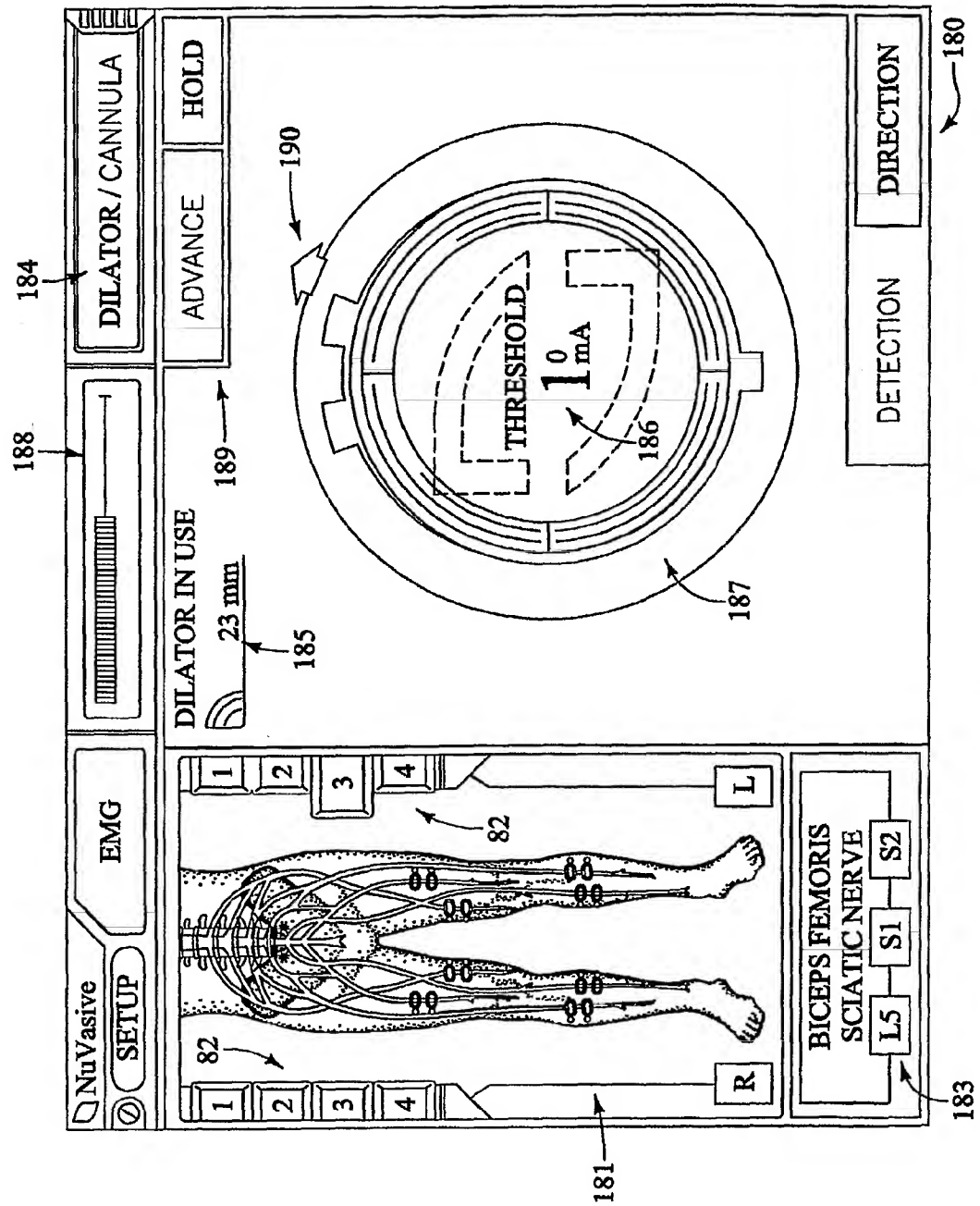


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/31768

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A 61 N 1/00

US CL : 607/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 6072

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,928,139 A (KOROS et al.) 27 July 1999 (27.07.1999), see entire document	1, 5, 9-10, 15
Y		2-4, 8, 16-18
Y	US 6,206,826 B1 (MATHEWS et al) 27 March 2001 (27.03.2001), see entire document.	2-4, 8, 16-18

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

07 January 2005 (07.01.2005)

Date of mailing of the international search report

Authorized officer

Mark W Bockelman

Telephone No. N/A

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230